



MacConkey Broth (Harmonized)

RDM-H-MCB-01

Principle

MacConkey Broth is a modification of the original bile salt broth recommended by MacConkey (1901) and Childs and Allen (1953). MacConkey broth is prepared in accordance with the harmonized principles of USP/EP/IP and used for identification of coliforms in pharmaceutical testing and microbial limit testing of pharmaceutical products and raw material used in pharmaceutical industries. It consists of pancreatic digest of gelatin, lactose monohydrate, dehydrated ox-bile and bromocresol purple. The pancreatic digest of gelatin provides amino acids and other growth factors. Lactose monohydrate is a carbon energy source for gram-negative lactose-fermenting bacilli. Ox bile inhibits the growth of gram-positive organisms. Bromocresol purple is act as the pH indicator. Bromocresol purple is highly sensitive in recording pH variation and changes it color from purple to yellow below pH 6.8.

Use: Recommended for identification of coliforms in pharmaceutical testing and microbial limit testing of pharmaceutical products and raw material used in pharmaceutical industries.

Contents*

Ingredients

	Gram/Litre
Pancreatic Digest of Gelatin	20.000
Lactose Monohydrate	10.000
Dehydrated Ox-Bile	5.000
Bromocresol Purple	0.010
pH at 25°C	7.3 ±0.2

* Formula adjusted for optimum performance and parameters

Directions: Dissolve 35.00 grams in 1000 ml distilled water. Boil to dissolve the medium completely and distribute in desire. Sterilize by autoclaving at 15 lbs. pressure (121°C) for 15 min, cool it to 42-45 °C and inoculate test sample aseptically.

Specimens types analyzed

Pharmaceutical samples, clinical and non-clinical samples etc.

Precautions to be taken

All the handling, experiments, storage, and discarding should be performed with the help of skilled and knowledgeable technicians and as per the established guidelines. The material should be disposed only after proper sterilization by autoclaving. Please go through the MSDS of the media to avoid any accidents or in emergency.

Performance and Evaluation

The expected performance of the medium is liable to use as per the direction on the label when stored at optimum conditions and within expiry date.

Quality Control

Appearance	Light beige colored free flowing, homogeneous powder
Reaction of 3.5% solution	7.3 ±0.2 at 25 °C
pH	7.10 – 7.50
Color and clarity of ready medium	Purple, clear opalescent solution
Growth Promotion properties	Best at ≤ 100 CFU at 32-37°C for 18-72 h

Indicative properties	Optimum at ≤ 100 CFU at 32-37°C for 18-48 h
Negative control	Performed using sterile distilled water

Different Microbial Response: Cultural characteristics observed after incubation at 30-35°C for 18-48 hours. Inoculum 50-100 CFU.

Organism	ATCC	Growth	Acid production	Gas production
<i>Escherichia coli</i>	8739	Luxuriant	Positive	Positive
<i>Escherichia coli</i>	25922	Luxuriant	Positive	Positive
<i>Klebsiella aerogenes</i>	13048	Luxuriant	Positive	Positive
<i>Salmonella typhimurium</i>	14028	Poor to Good	Negative	Negative
<i>Staphylococcus aureus</i>	6538	Inhibited	--	--
<i>Staphylococcus aureus</i>	28923	Inhibited	--	--

Cultural characteristics observed after incubation at 42-44°C for 18-48 hours. Inoculum 50-100 CFU.

Organism	ATCC	Growth	Acid production	Gas production
<i>Escherichia coli</i>	8739	Luxuriant	Positive	Positive
<i>Staphylococcus aureus</i>	6538	Inhibited	--	--

Storage and Shelf Life: The product is highly hygroscopic; keep the container tightly closed at all times and store it properly as per the conditions mentioned on the label. The declared expiry is valid only when stored as per the conditions mentioned on the label.

Note: Sterilize media immediately after reconstitution.

Disposal: To avoid the contamination or propagation of any hazardous microbes the used, unusable or modified preparation of this product must be disposed after autoclaving after completion of task.

Reference

1. British Pharmacopoeia, 2016, The Stationery office British Pharmacopoeia.
2. Childs, E., and L. A. Allen. (1953). Improved methods for determining the most probable number of Bacterium coli and of Streptococcus faecalis. J. Hyg. Camb. 51:468-477
3. Difco Manual (1998). 11th Edition. Difco Laboratories., Division of Becton Dickinson and Company, Sparks, Maryland, USA.
4. European Pharmacopoeia, (2011), European Dept. for the quality of Medicines.
5. Indian Pharmacopoeia, (2018), Govt. of India, the Controller of Publication, New Delhi.
6. Japanese Pharmacopoeia, 2016.
7. MacConkey, A. (1901). Centr. Bakt. 29:740.
8. The United States Pharmacopoeia, (2014), The United States Pharmacopoeial Convention. 12601 Twinbrook Parkway, Rockville, MD 20852.

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